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10/635,264	08/06/2003	Sung Soo Kim	0209.1003	1387

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EXAMINER	
ANGELL, JON E	

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1635	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/635,264	KIM ET AL.	
	Examiner	Art Unit	
	J. Eric Angell	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2006 and 02 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,3,6-8 and 10-15* is/are pending in the application.

4a) Of the above claim(s) *2,3 and 6-8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Action is in response to the communications filed on 12/27/2006 and 4/2/2007.

The amendment filed 4/2/2007 is acknowledged and has been entered.

Claims 2, 3, 6-8 and 10-15 are currently pending in the application and are addressed herein.

1. Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Status of the Claims

Claims 2, 3, 6-8 and 10-15 are currently pending.

2. Newly amended claims 2, 3, 6-8 are now directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: previous claims 2, 3, 6-8 were drawn to a pharmaceutical composition comprising a genetically modified cell and a method of making the genetically modified cell. Claims 2, 3, 6-8 now read on a method for preventing cyclophilin A-induced cytotoxicity in transplanted cells using a cell that overexpresses a cyclosporin with PPI activity. This new invention is related to the elected invention as product (elected invention, which includes a method of making the product) and process of use (the new invention). The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a

materially different process of using that product. See MPEP § 806.05(h). In the instant case product as claimed can be used in a materially different process of using that product. For instance, the cell which overexpresses cyclophilin A can be used to produce and isolate recombinant cyclophilin A. Furthermore the search required for the new claims, includes searching for a method of preventing cytotoxicity, which is not required for the elected claims. Accordingly, a burden exists for searching the newly amended claims 2, 3, 6-8 with the invention of claims 10-15.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 2, 3, 6-8 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Applicants anticipated the withdrawal of claims 2, 3, 6-8 from consideration, as indicated in the response filed 12/27/2006 (see page 4), and preemptively argue that the search required for the new claimed subject matter would not be a burden. This is not persuasive for the reasons indicated above.

Claims 10-15 are examined herein.

Claim Rejections - 35 USC § 112, 2nd paragraph

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 10-12 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 is drawn to:

> A pharmaceutical composition for preventing cyclosporin A-induced cytotoxicity by the overexpression of cyclophilin with PPIase activity in a transplanted cell, wherein the transplanted cell is an H0c2 rat cardiac myoblast transfected with a vector expressing a CypA gene.

Therefore, claim 10 only sets forth the intended use of a pharmaceutical composition, but does not set forth what the actual pharmaceutical composition is comprised of, thus the claims are indefinite as the metes and bounds of the pharmaceutical composition cannot be determined. Claims 11 and 12 are included in the rejection because they depend on claim 10.

5. Claim 14 recites the limitation "the CypA gene" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 112, 1st paragraph

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 10-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

MPEP §2163.06 notes:

If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981).

MPEP §2163.02 teaches that:

Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application.

MPEP §2163.06 further notes:

When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure.

Claims 10 and 13 include the limitation "H0c2 rat cardiac myoblast". However, a text search of the specification did not identify any explicit disclosure of a "H0c2 rat cardiac myoblast". Furthermore, no implicit support for this limitation could be found. Additionally, it is noted that a search of the prior art did not identify any H0c2 myoblasts. Applicants have stated that support for the new claims can be found throughout the specification, including Example 5. It is noted that Example 5 discloses H9c2 rat cardiac myoblasts, not H0c2 rat cardiac myoblast. Therefore, the claims are appropriately rejected under 35 U.S.C. 112, 1st paragraph for encompassing subject matter which was not provided in the original disclosure.

To the extent that the claimed compositions and/or methods are not described in the instant disclosure, claims 10-15 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

8. Claims 10, 12, 13 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims encompass "cyclophilin A with PPIase activity". Given the broadest reasonable interpretation of the claims consistent with the specification, the phrase "cyclophilin A with PPIase activity" is interpreted as encompassing any variant, fragment of derivative, of cyclophilin A that has PPIase activity. This would include functional homologs which are structurally unrelated to wild-type cyclophilin A. Therefore, the claims encompass a genus of cyclophilin A molecules, that is indeterminate in size, but could encompass an enormous number of different "cyclophilin A molecules".

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making

the claimed product, or any combination thereof. In this case, the claims encompass a genus of "cyclophilin As that have PPIase activity" while the specification only discloses two species of this genus, wild-type cyclophilin A, and one mutant that has W121F substitution. Accordingly there is insufficient disclosure provided such that one of skill in the art would be able to readily identify any cyclophilin A having PPIase activity, other than the two that are explicitly disclosed, without performing additional experimentation. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of molecules, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Therefore, only the two explicitly disclosed species: wild type cyclophilin A and W121F cyclophilin A, meet the written description provision of 35 U.S.C. §112, first paragraph.

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).)

Response to Arguments

9. Applicant's arguments filed 12/27/2006 have been fully considered.

The amendment to the claims is sufficient to obviate the rejection of claims under 35 U.S.C. 102(e) and 35 U.S.C. 112, 2nd paragraph. Thus applicant's arguments are moot as they apply to these rejections.

The declaration under 37 CFR 1.132 filed 12/27/2006 is sufficient to overcome the rejection of claims based upon Hong et al. (FASEB J, 2002).

Conclusion

10. No claim is allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Monday-Thursday 8:00 a.m.-6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. E. Angell/
Primary Examiner
Art Unit 1635